510(k) Summary of Safety and Effectiveness in accordance with 21 CFR 807.92

(a) (1) **Submitted by:**

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Contact Person: Dr. Choon Meng TING, M.D.

Position/Title: President/CEO

Date of Preparation: June 20, 2013

Trade Name: HealthSTATS BPro® Ambulatory Blood Pressure Monitoring System with BProSOft CASP® PC software

Common/Classification Name: System, Measurement, Blood-pressure, Central, Non-invasive

Product Code: 74 DXN, 21 CFR § 870.1130

Class: Class II

(3) **Predicate Device(s):**

K060315	BPro Ambulatory Blood Pressure Monitoring with BProSOft application software
K072593	A-PULSE CASP PC application software – Central Aortic Systolic System
K110603	Mobil-O-Graph 24h PWA with Hypertension Management Software Client Server (HMS-CS 4.3)

Reason for Submission: New Device

(4) **Description of Device:**

HealthSTATS BPro® Ambulatory Blood Pressure Monitoring System with BProSOft CASP® PC software is a noninvasive ambulatory blood pressure monitoring system based on arterial tonometry at the radial artery of the wrist. The system consists of three main elements:

- BPro wrist-mounted tonometric monitor (listed device **K060315**).
- BProSoft CASP report management software, a PC-based computer program (new/added measurement function).
- BPCalibrator MC3000 oscillometric blood pressure monitor [listed device, **K051546**] for calibration of BPro monitors.

Once the BPro is calibrated using the BPcalibrator oscillometric device, it is capable of measuring and recording systolic pressure, diastolic pressure and pulse rate over a period of 24 hours. Arterial pulse waveforms obtained over the 24 hour period are used by the BProSoft CASP PC software to calculate central aortic systolic pressure (CASP).

(5) **Intended use:**

Blood pressure is measured in millimeters of mercury (mmHg) and is typically represented by two values: systolic pressure and diastolic pressure. The systolic pressure represents the pressure in the blood vessels when the heart contracts (pumps), while the diastolic pressure is the pressure when the heart relaxes and blood fills the heart. The calculation of central aortic systolic pressure (CASP) which is determined from arterial pulse waveform analysis can provide additional useful information on the condition of the heart.

Blood pressure fluctuates throughout the day. Specific ranges are associated with normal, hyper- and hypotension. Ambulatory blood pressure measurement devices provide useful 24 hour blood pressure profiles This submission includes the addition of ambulatory central aortic systolic pressure measurement. Evaluation of blood pressure profiles can assist with diagnosis of specific cardiovascular conditions.

Indications for Use:

The BPro® system is a noninvasive ambulatory central blood pressure monitoring system based on tonometry at the radial artery of the wrist. The system consists of a BPro® wrist-mounted tonometric monitor, and a BPCalibrator MC3000™ oscillometric blood pressure monitor for calibration, and BProSOft CASP® Software, a PC-based computer program.

Before each measurement session, the wrist-mounted tonometric device is calibrated using the oscillometric monitor. Once calibrated, the BPro wrist device is capable of recording and displaying up to 96 measurements of systolic and diastolic blood pressure, pulse rate, and radial pulse waveform over a 24-hour period. The central aortic systolic pressure (CASP) is calculated utilizing the recorded radial pulse waveform and BProSOft CASP® PC software.

BProSOft CASP® PC software is used to provide data to qualified medical personnel for the purpose of assessing the patient's cardiac health via blood pressure readings taken during daily activity for up to 24-hour period.

The BPro system is intended for use on patients who are eighteen (18) years and older and who have a palpable radial pulse.

The BPro system is intended only for measurement, recording, and display. It makes no diagnosis.

Caution: Federal law (U.S.A.) restricts this device to sale by or on the order of a physician or other licensed practitioner.

(6) **Technological Characteristics:**

The BPro Ambulatory Blood Pressure Monitoring System combines two established measurement methods used by the referenced predicate devices:

- BPro ambulatory blood pressure monitoring at the wrist using arterial tonometry
- Arterial pulse waveform analysis to determine the CASP.

The BPro monitor is applied to the wrist with a pressure transducer placed over the radial artery. The monitor has a size and weight similar to a sports type wrist watch.

An embedded microcontroller supervises the actions of the monitor including scheduled measurements, status reporting, and serial data communications with the host PC.

The BProSOft CASP® PC software utilizes arterial pulse waveform analysis to calculate ambulatory central aortic systolic pressure (CASP), which is in addition to the cleared blood pressure parameters of the BPro® Ambulatory Blood Pressure Monitoring System.

(b) (1) **Non-Clinical Tests Submitted:**

The BPro monitor device meets applicable standards for medical device electrical safety, electromagnetic compatibility, shock and vibration, and environment (temperature and humidity).

Materials utilized in skin contact surfaces were reviewed for conformance with biocompatibility requirements. The materials met the requirements.

The BProSOft CASP PC software was verified to requirements and validated to meet intended use. System level risk, hazard, and failure

mode analysis was performed and residual risks were determined to be acceptable.

(2) **Clinical Tests Submitted:**

The BPro Ambulatory Blood Pressure Monitoring System has been previously clinically validated and cleared for the measurement of ambulatory systolic and diastolic pressure and pulse rate measurements.

The BProSOft CASP PC Software is an upgraded PC Software application that adds the CASP measurement function. BProSOft CASP PC Software has been clinically studied with the BPro monitor in comparison to a listed predicate device for the derivation of central aortic systolic pressure (CASP). Test results confirm the accuracy of the BProSOft CASP measurement consistent with the predicate device measurements within the stated accuracy claims.

(3) **Conclusions from Tests:**

As described in (b)(1) and (b)(2) above, the testing demonstrates that the HealthSTATS BPro® Ambulatory Blood Pressure Monitoring System with BProSOft CASP® PC software is as safe and effective as, and functions in a manner equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

March 11, 2014

HealthSTATS International Pte. Ltd.
c/o Mr. Stephen Gorski
Imagenix, Inc.
S65 W35739 Piper Road,
Eagle, WI 53119

Re: K131916
Trade/Device Names: HealthSTATS BPro® Ambulatory Blood Pressure Monitoring System with BProSOft CASP® PC Software
Regulatory Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (Two)
Product Code: DXN
Dated: January 29, 2014
Received: January 31, 2014

Dear Mr. Gorski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

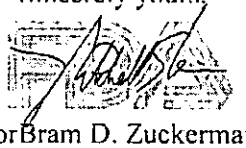
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K131916**

Device Name: HealthSTATS BPro® Ambulatory Blood Pressure Monitoring System with BProSOft CASP® PC software

Indications for use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND / OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Concur

FDA Date: 2014.03.11 16:40:00 -04'00'

for Bram Zuckerman